DEC 2 3 2005

510(k) Summary K051041

Common / Usual Name:	External Insulin Infusion Pump
Classification Name:	Insulin Infusion Pump
Class:	Class II; 21 CFR §880.5725
Panel:	General Hospital
Product Code:	80 LZG

Establishment Information

Sponsor:	TheraSense, Inc. 1360 South Loop Road Alameda, CA 94502
Contact Person: Title: Telephone: Facsimile:	Andrea L. Ruth Sr. Associate, Regulatory Affairs (510) 749-6360 (510) 239-2799
Predicate Device	Medtronic MiniMed 515
Predicate Device Manufacturer	Medtronic MiniMed, 18000 Devonshire St., Northridge, CA 91325

Performance Standards, Section 514 of the Act

No performance standard(s) or special controls applicable to this device have been promulgated under Section 514 of the Act.

Comparison of the Technological Features of the New Device and Predicate Device

The new and predicate devices have similar materials and basic design and technology.

Substantial Equivalence Comparison and Rationale

The Abbott Diabetes Care Insulin Pump (Pump) is substantially equivalent to the Medtronic MiniMed Paridigm 515.

The Pump has the same target users and operating environment as predicate devices. A comparison of product features and performance characteristics of the previously cleared Medtronic MiniMed Paridigm 515 [510(k) #K040676] and the TheraSense, Inc. Insulin Pump is provided within the substantial equivalence discussion below.

510(k) K051041

The insulin pumps are all intended for use in home and clinical settings for the control of blood glucose levels in diabetes. The indication for use statement for the proposed Insulin Pump has the same elements as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2005

Ms. Mary Rose
Supervisor, Regulatory Affairs
Abbott Diabetes Care, Incorporated
1360 South Loop Road
Alameda, California 94502

Re: K051041
Trade/Device Name: Abbott Diabetes Care Insulin Pumps
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: December 6, 2005
Received: December 6, 2005

Dear Ms. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

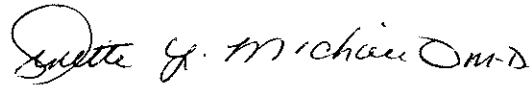
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K051041

Device Name: Abbott Diabetes Care Insulin Pumps
Indications for Use: The Insulin Pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

for ADW
12/23/05

K051041